ELISABETH M. GEORGE

Education

- Northeastern University, Boston, MA — Masters Certificate in Engineering Management
- Boston University — Bachelor in Science in Biomedical/Electrical Engineering
- Boston Latin School

Professional Summary

- More than 15 years of increasing responsibility in quality and regulatory affairs
- More than 10 years of "hands on" and strategic supervisory/management experience
- Strong, multi-disciplinary technical and professional skills

Professional Experience

December 2001- Present — **Philips Medical Systems** (formerly Agilent Technologies, formerly Hewlett-Packard) — **Vice President of Quality, Regulatory, Sustainability & Product Security**

Manage strategic planning and technical aspects for quality, regulatory, security, environmental and sustainability compliance for seven design and manufacturing facilities. Responsible for technical team ensuring worldwide compliance in product submissions, post market surveillance, quality systems (ISO13485, 21CFR), environmental management system (ISO14001) and business systems for the following product families: patient monitoring, cardiographs, information systems, wireless devices, in vitro diagnostics, homecare products, defibrillators and associated services and supplies. Responsible for ISO 14971 Risk Management Program. Focal point for PMS for Training Systems, HIPAA, JCAHO and Product Regulatory Submissions Strategy and Requirements. PMS Supplier Quality Network and Product Security Council Q&R Lead. FDA Emergency Response Contact for PMS. Member of Biohazard Council.

Jan. 1998 – December 2001 — **Philips Medical Systems** (formerly Agilent Technologies, formerly Hewlett-Packard) — **WW Quality & Regulatory Director**
Cardiac and Monitoring Products - Patient Monitoring Division, Point of Care Diagnotics Division and Congestive Heart Failure Home Care Products
Andover MA, Pittsburgh PA, Palo Alto CA and Boeblingen Germany

Manage strategic planning and technical aspects for quality and regulatory compliance and WW submissions programs(US - 510(k), PMA and Rest of World for medical, information and telecom systems for domestic and international laws and regulations for software and hardware solutions. Manage quality and regulatory personnel . Define, implement and maintain QSR, EN46001 and ISO13485 quality programs for Patient Monitoring Division, Point of Care Business and CHF Home Products Business. Supported ISO 14001 certification. Interface with FDA, European Competent Authorities, Canadian, AP and South American Ministries of Health on submissions and vigilance reporting and analysis. Responsible for EMC, LVD, RTT&E, MDD and IVD Compliance. Champion quality improvement programs including six sigma programs. Manage engineering personnel located in US and International Facility. Member of executive staff for $800 million patient monitoring, clinical information, point of care diagnostic, home care and wireless solutions. Responsible for FCC petition for medical telemetry radio frequency management program and PTT international submissions and licenses. Responsible for petition for Fetal Scalp Electrode with FDA to extend utilization. Define technical requirements necessary for meeting country patient safety regulations. Responsible for third party partnership quality and regulatory agreements for software and hardware contracts. Interface with cross-functional project management to support development and product life cycle management. Manage post market surveillance investigations and corrective action programs. Six Sigma training classes and project management of Six Sigma Black Belts direct reports. Partnership and contract Q&R analysis for OEMs and future potential procurement.

Oct. 1993 – Dec. 1997 **Hewlett-Packard Company** **Regulatory Manager**
Healthcare Solutions Group
Patient Monitoring, Healthcare Management & Cardiology Products Divisions
Andover, MA

Responsible for regulatory submissions and strategy definition for medical systems for domestic and international laws and regulations for software and hardware solutions including bedside patient monitors(fixed & mobile), clinical information systems, central stations, cardiographs and defibrillators. Defined, created and implemented a quality system in Healthcare Management Division.

May. 1993 – Oct. 1993 **Sterimatics Corporations** **Quality/Regulatory Manager**
a subsidiary of Millipore
Bedford, MA

Manage technical and administrative aspects of quality, regulatory and documentation control departments for a military/medical device design and manufacturing operation. Setup quality program including training program. Interfaced with regulatory agencies.

Nov. 1991 – May 1993 **Haemonetics Corporations** **Equipment Operations Manager**
Braintree, MA

Managed production schedules and staff. Provided technical guidance for pilot production and low to high volume production lines in the manufacture of sophisticate electromechanical blood washing and separating equipment. Reduced manufacturing floor space required by 50% while increasing output by 30% using cell design and time study principles. Eliminated kit pulling for monthly scheduled builds of up to 250 machines by implementing min/max system to support daily shipments. Responsible for training personnel and implementing SPC improving out of box quality levels 20% over 6 months. Trained personnel in manufacturing processes, policies and procedures to meet quality and regulatory requirements.

Dec. 1989 – Nov. 1991 **Haemonetics Corporations** **Director of Quality & Regulatory**
Braintree, MA

Managed technical and administrative aspects of quality and regulatory departments. Extensive experience with supplier selection, qualification and management. Significant experience with new product hardware and software introduction and current product maintenance. Responsible for UL, CSA, TUV and City of LA applications, renewals and audits . Responsible for quality and regulatory programs for electromechanical and disposable equipment design, manufacturing and distribution facilities. Reduced quality control inspection and testing of finished devices by 75% through use of SPC and training of manufacturing personnel. Principal contact with FDA, Ministries of Health and DCAS. Preparted product approval and vigilance submissions. Established policies, procedures for document control systems. Established comprehensive ESD Program and audit program. Certified quality auditor.

Oct. 1983 – Dec. 1989 **Electro-Optics, a division of Honeywell** **Quality Assurance Manager**
Lexington, MA

Managed quality operations in the manufacturing of infrared imaging systems. Managed Program Managers, Engineers, Technicians, Inspectors and Data Administrators providing support on multiple large contracts for guidance, navigational and investigation systems for commercial and military use. Established and managed quality policies and procedures as required for Mil-Q-9858A. Established ESD and audit programs including training for production and technical personnel. Interfaced and coordinated with resident and non-resident Defense Contractors Administrators and foreign customers on technical and quality audits and inspections. Performed reliability analysis for products per contractual requirements. Focal point for operational correction action teams, cost of quality teams and business improvement

programs reducing processing cost up to 40%. Trained personnel in SPC and QA Procedures. Chaired Management Training Program. Generated cost and task proposals for new and follow on contracts. Managed quality assurance tasks for production and engineering contracts. Evaluated and certified equipment during design, manufacture and supplier certifications. Generated monthly customer reports including SPC, trend data and failure analysis tasks. Follow up contracts proposal generation and daily interface with resident customers(US and Foreign Government Representatives).

Additional Experience

- MicroSwitch, a division of Honeywell – Test Engineer: 1982-1983
- Stone and Webster Engineering Corp. – Control Systems Engineer: 1980-1982
- Teledyne Crystalonics – Junior Engineer: 1979-1980
- Boston Children's Hospital – Orthopedic Lab Engineer Technician: 1976-1979

Miscellaneous

- Experience with SPC, TQM, Supplier Certification, Risk Analysis and Taguschi Principles
- Extensive training in Total Quality Management and Validation Processes
- Training in Sales and Marketing Principles and Practices, Supplier Certification, ISO9000/EN46000/ISO13485, MDD, LVD, IVD, EMC, FCC, RTT&E, Manufacturing Cell Design, ISO 14971 and Clinical Use and Practice of Medical Equipment
- QSR Training and Certifications
- Certified Trainer in Visual Factory Design, Quality Auditing, Regulatory Submissions
- Held Secret Level Security Clearance 1984-1989
- Fluent in German
- CPR and Basic First Aid Certified
- Assisted in paper, "Mouse Bone Collagenase", Archives Biochemical & Biophysics Vol. 189, #1, 7/78

Memberships/Affiliations

Institute of Electrical and Electronics Engineers since 1979
Biomedical Engineering Society since 1977
Who's Who in Professional and Executive Women since 1986
American Society of Quality since 1989
HIMA (AdvaMed) since 1991
American Association for Medical Instrumentation since 1991
Regulatory Affairs Professionals since 1993

Chairperson of Family Services Committee and Education Program Committee at JCC 1992-1998
Co-chairperson of Social Activities Committee at JCC 1994-1998
Board of Director's at JCC 1995-1997
Member of AdvaMed Medical Technology Preparedness Council since 2001